DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 17-854/S-041
NDA 17-862/S-048
NDA 18-821/S-020

A.H. Robins
c/o: Wyeth-Ayerst Research
Attention: Mary Alice Dankulich
Associate Director, Worldwide Regulatory Affairs
150 B3 N. Radnor-Chester Road
St. Davids, PA 19087

07 NOV 2001

Dear Ms. Dankulich:

Please refer to your supplemental new drug applications dated May 9, 2001, received May 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reglan (metoclopramide) Tablets, Injection, and Syrup.

These "Changes Being Effected" supplemental new drug applications provide for multiple revisions to the DESCRIPTION, CLINICAL PHARMACOLOGY, PRECAUTIONS, ADVERSE REACTIONS, and HOW SUPPLIED sections of the package inserts.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package inserts submitted May 9, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

However, at the next printing of these package inserts, please revise the third paragraph of the PRECAUTIONS section, General subsection to read, “Because metoclopramide produces a transient increase in plasma aldosterone, certain patients, especially those with cirrhosis or congestive heart failure, may be at risk of developing fluid retention and volume overload. If these side effects occur at any time during metoclopramide therapy, the drug should be discontinued.”

The Division may be notified of these changes in the subsequent annual reports.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Melodi McNeil, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research